

## **REMARKS**

Claims 14-22 are pending in the present application. Claims 23-33 and 47 have been canceled without prejudice.

Claim 14, 17, and 19 have been amended to more particularly describe and claim the invention. Specifically, claim 14 has been amended to recite that the reservoir is disposed about the balloon and the sponge coating is in fluid communication with the reservoir. Support for this amendment is found, *inter alia*, on page 4, paragraphs [0025] and [0026] of the specification. Claims 17 and 19 have been amended to correct typographical errors and therefore no new matter has been added.

### **I. OBJECTIONS TO THE DRAWINGS**

The Examiner objected to the drawings under 37 C.F.R. 1.83(a). The Examiner stated that since claim 18 recites a perfusion lumen, such feature must be shown in the figures or the feature should be canceled from the claims. Applicants propose that Figure 2c be added. This figure is the same as originally filed Figure 2b with the addition of the perfusion lumen 17. Support for the perfusion lumen is found on page 5, paragraph [0026] of the specification. Therefore the applicant believes that all objections to the drawings have been overcome and should be withdrawn.

### **II. OBJECTIONS TO THE SPECIFICATION**

The Examiner objected to the amendments made to the specification, filed on May 6, 2004 under 35 U.S.C. §132 as introducing new matter. Contrary to the assertion in the Office Action, the addition of the perfusion lumen 17 in Figure 2c and is not new matter. The perfusion lumen, as claimed in claim 18 is supported in the specification, specifically at page 5, paragraph [0026] of the specification. Therefore, addition of the perfusion lumen in Fig. 2c is not new matter.

### **III. CLAIM REJECTIONS UNDER 35 U.S.C. § 103**

#### **A. Claims 14, 17-23, 25, 27-33 and 47 Are Patentable Over U.S. Patent No. 5,458,568 to Racchini In View of U.S. Patent No. 5,304,121 to Sahatjian**

The Examiner has rejected claims 14, 17-23, 25, 27-33 and 47 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,458, 568 to Racchini. ("Racchini ") in view of U.S. Patent No. 5,304,121 to Sahatjian ("Sahatjian"). Specifically, the Examiner stated that Racchini teaches all of the limitations of the claims except for specifically reciting

a non-hydrogel polymer having a plurality of voids. The Examiner further stated that Sahatjian teaches the use of a non-hydrogel polymer having a plurality of voids and that it would have been obvious to one of ordinary skill in the art to modify the sponge coating of Racchini with the non-hydrogel polymer sponge coating of Sahatjian. Applicant respectfully disagrees with this rejection.

In order to establish a *prima facie* case of obviousness of a claimed invention, all the limitations must be taught or suggested by the prior art. MPEP 2143.03 citing *In re Royka*, 490 F.2d 981 (CCPA 1974).

As currently amended, independent claim 14 and its dependent claims 17-22, are directed to a medical device for delivering a biologically active material to a desired location in a body lumen of a patient. The medical device is comprised of an expandable portion which is inserted or implanted into a body lumen. The expandable portion expands in response to inflation pressure which fills the lumen. The expandable portion is primarily comprised of a balloon, a reservoir disposed on the balloon and a sponge coating. The reservoir is defined by a membrane having a plurality of pores therein, and is capable of containing a biologically active material. The reservoir is further connected to a reservoir lumen that fills the reservoir with a biologically active material. The reservoir is in fluid communication with the biostable sponge coating disposed on the reservoir. The sponge coating, generally, is comprised of a non-hydrogel polymer having a plurality of voids.

Racchini does not teach or suggest a medical device having a reservoir, for containing a biologically active material, disposed about a balloon. Also, Racchini does not teach that a reservoir, disposed on a balloon, is defined by a membrane having a plurality of pores. Racchini teaches a balloon made of a non-wetting membrane, with no reservoir disposed on the balloon's surface.

Sahatjian does not remedy Racchini's deficiency. Sahatjian also, does not teach or suggest a method of making a medical device where a reservoir, which is defined by a membrane having a plurality of pores, is disposed about a balloon. Similar to Racchini, Sahatjian only discloses a balloon catheter, with no reservoir, in which a coating is disposed on the outside of the balloon. Therefore, Racchini and Sahatjian, individually or in combination do not render claims 14 and 17-22 obvious. Therefore the Examiner's rejection should be withdrawn.

**B.      Claims 14-33 and 47 Are Patentable Over Racchini In View  
U.S. Patent Nos. 6,099,562; 6,284,305; 6,620,194 to Ding *et al.***

The Examiner has rejected claims 14-33 and 47 under 35 U.S.C. § 103(a) as being unpatentable over Racchini in view U.S. Patent Nos. 6,099,562; 6,284,305; 6,620,194 to Ding *et al.* (hereinafter the “Ding patents”). The Applicants respectfully traverse the rejection.

These Ding patents cannot be applied as a basis for an obviousness rejection. Pursuant to 35 U.S.C. § 103(c) and M.P.E.P. § 706.02(k), a reference, which qualifies as prior art only under one or more of subsections 35 U.S.C. § 102 (e), (f), and (g), does not qualify as a prior art reference against an application if (1) such application was filed on or after November 29, 1999, and (2) the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

These Ding patents did not issue until after the effective filing date of the present application, April 19, 1998, and thus can only qualify as prior art under 35 U.S.C. § 102(e). The present application was filed on February 7, 2002, after November 29, 1999. In addition, at the time the present invention was made, the inventions of Ding and the inventor of the present application were subject to an obligation to assign their respective inventions to Schneider (USA), Inc. Pursuant to this obligation, Ding and the present application were assigned to Schneider (USA), Inc. as shown by the documents in Appendices A, B and C. In particular, as shown in Appendix A, the assignment to Schneider (USA) Inc. for Patent No. 6,099,562; was executed on December 9 and 20, 1997 and was recorded on Dec. 22, 1997, at Reel, 008917 Frame 0115. As shown in Appendix B, the assignment to Schneider (USA) Inc. for Patent No. 6,284,305 and its continuation Patent No. 6,620,194 was executed on December 9 and 20, 1997 and was recorded on May 18, 2000, at Reel, 010830 Frame 0942. Appendix C includes an Assignment from the inventors of the present invention to Schneider (USA), Inc. and a Notice of Recordation showing that the Assignment was executed on April 9, 1998 and was recorded in the USPTO on April 14, 1998, at Reel 009155, Frame 10754.

Thus, the Ding patents do not qualify as prior art that can be used in a 35 U.S.C. § 103(a) rejection. Accordingly, withdrawal of this rejection and allowance of the claims are respectfully requested.

**C. Claims 15-16, 24, 26, 33 and 47 are Patentable Over Racchini  
In View Sahatjian as applied to claims 14, 17-23, 25 and 27-33  
and in further view of Patent No. 5,447,724 to Helmus et al.**

Examiner also rejects claims 15-16, 24, 26, 33 and 47 as being unpatentable under 35 U.S.C. §103(a) over Racchini in view of Sahatjian as applied to claims 14, 17-23, 25 and 27-33 and in further view of Patent No. 5,447,724 to Helmus et al.

As stated above, Racchini in view of Sahatjian does not teach or suggest the present invention. Moreover Helmus does not remedy the deficiencies of this reference. Helmus, like Racchini and Sahatjian, does not teach a reservoir for containing a biologically active material, disposed on a balloon. Furthermore, Helmus does not teach or suggest that the reservoir is defined by a membrane having a plurality of pores or that the reservoir is connected to a reservoir lumen for filling the reservoir. Therefore, Helmus either alone or in combination with Racchini and Sahatjian does not render the present claims obvious.

**IV. DOUBLE PATENTING REJECTION**

Claims 13-33 and 47 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-17 of U.S. Patent No. 6,099,562 to Ding (“the Ding ‘562 patent”) in combination over Racchini.

As cited before, in order to establish a *prima facie* case of obviousness of a claimed invention, all the limitations must be taught or suggested by the prior art. MPEP 2143.03 citing *In re Royka*, 490 F.2d 981 (CCPA 1974). Again, Racchini does not teach or suggest a medical device with a reservoir is disposed about a balloon. Moreover, the Ding ‘562 patent does not remedy the deficiencies found in Racchini. The Ding ‘562 patent also does not teach or suggest a reservoir for containing a biologically active material disposed about a balloon.

Therefore the present claims are not obvious in view of Racchini and the Ding ‘562 patent.

### **CONCLUSION**

Applicants submit that the present claims satisfy all of the criteria for patentability and are in condition for allowance. Withdrawal of the Examiner's rejections and allowance of the application are earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same. No fee is believed due for the Amendment. Should any fee be required, please charge such fee to Jones Day Account No. 50-3013.

Respectfully submitted,

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*Enclosure*